time for the reporters to make the necessary changes to their computerized systems.

During this transitional period FDA will accept both the newly effective Forms 3500 and 3500A and the prior versions of the forms. Information concerning the reuse of the product (new question D8) and the name and address of the reprocessor (new question D9) can be provided in section H10 on the prior version of form 3500A (OMB approval date, November 2002). Reporters may continue to use the prior version of Forms 3500 and 3500A until [*insert date 6 months after date of publication in the* **Federal Register**]. During this 6-month period, the prior versions and the instructions will be available on FDA's Center for Devices and Radiological Health MDR Web site at *http://www.fda.gov/cdrh/mdr/mdr-forms.html*.

III. Availability of Forms

The newly revised MedWatch forms are available at FDA Form 3500 *http://www.fda.gov/medwatch/safety/3500.pdf* and FDA Form 3500A *http://www.fda.gov/medwatch/safety/3500a.pdf*.

The instructions for the revised forms are available at FDA Form 3500 *http://www.fda.gov/medwatch/report/consumer/instruct.htm* and FDA Form 3500A *http://www.fda.gov/medwatch/report/instruc.htm*.

Dated: January 30, 2004.

Beverly Chernaik Rothstein,

Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.

[FR Doc. 04–3333 Filed 2–13–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0834]

Draft Guidance for Industry on Labeling for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling.'' The draft guidance is intended to assist applicants in developing labeling for new drug applications (NDAs) for such drug products. This is the third draft of the guidance, which initially issued in September 1999.

DATES: Submit written or electronic comments on the draft guidance by April 19, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Margaret Kober, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4243.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling.'' The draft guidance describes the recommended labeling for health care providers and patient instructions for inclusion in NDAs. A draft of this guidance was first issued on September 27, 1999 (64 FR 52100). However, on September 10, 2002, the agency withdrew the draft guidance (67 FR 57432), pending consideration of the results from the National Institutes of Health (NIH) Women's Health Initiative (WHI). In the **Federal Register** of February 3, 2003 (68 FR 5300), the agency issued a second draft reflecting the agency's thinking after considering the results of the WHI substudy concerning overall risks and benefits of hormone therapy for postmenopausal symptoms.

The agency is issuing this third draft guidance to address comments received, to incorporate new study results from the WHI, and to better inform prescribers and patients regarding the availability of the lowest effective dose for these drug products. This third draft supersedes the second draft and reflects the agency's thinking after considering these issues. Further revisions to the guidance may be necessary as additional information becomes available.

On May 31, 2002, the WHI study of conjugated estrogens 0.625 milligram (mg)/day (CE) plus medroxyprogesterone acetate 2.5 mg/day (MPA) in postmenopausal women was stopped after a mean of 5.2 years of followup because the test statistic for invasive breast cancer exceeded the stopping boundary for this adverse effect and the global index statistic supported risks exceeding benefits. Data on the major clinical outcomes through April 30, 2002, regarding increased risks for invasive breast cancer, heart attacks, strokes, and venous thromboembolism rates, including pulmonary embolism, became available July 17, 2002. On March 17, 2003, additional information was published about health-related quality of life.

The Women's Health Initiative Memory Study (WHIMS), a substudy of the WHI, was published on May 28, 2003. It concluded that women treated in the study with conjugated estrogens 0.625 mg combined with medroxyprogesterone acetate 2.5 mg have a greater risk of developing probable dementia than those on placebo. Detailed information about WHIMS is available at *http://www.nih.gov/PHTindex.htm*.

This third draft of the guidance retains and updates the labeling recommendations regarding the results of the WHI study and recommends adding risk information related to the results of the WHIMS study to appropriate sections of the labeling, including the boxed warning. It also adds to the WARNINGS section that use of estrogen-containing products may increase the risk of mammographic abnormalities. In addition, because it is unknown whether risks for postmenopausal women prescribed estrogen-containing products for the treatment of moderate to severe vasomotor symptoms and moderate to severe symptoms of vulvar and vaginal atrophy differ depending on the dose prescribed, the guidance recommends

that labeling include a statement as to whether or not the lowest effective dose for the product has been identified.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on labeling for noncontraceptive estrogen drug products for the treatment of moderate to severe vasomotor symptoms and moderate to severe vulvar and vaginal atrophy symptoms. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3330 Filed 2–11–04; 11:58 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting. The meeting will be open to the public.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: March 16, 2004, 9 a.m.–1:15 p.m., EST.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The full ACCV will meet on Tuesday, March 16, from 9 a.m. to 1:15 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1–800–619–2521 on March 16 and providing the following information:

Leader's Name: Thomas E. Balbier, Jr.

Password: ACCV.

Agenda: The agenda items for March 16 will include, but is not limited to: a presentation on the draft Tetanus and Diphtheria Vaccine Information Statements; an update on thimerosal lawsuits; a discussion of changes to the Vaccine Injury Table, including addition of Influenza vaccines; and updates from the Division of Vaccine Injury Compensation, the Department of Justice, and the National Vaccine Program Office. Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Special Programs Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 16C–17, Rockville, MD 20857 or by e-mail at *clee@hrsa.gov.* Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period on the audio conference call. These persons will be allocated time as time permits.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Special Programs Bureau, Health Resources and Services Administration, Room 16C–17, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: (301) 443–2124 or e-mail: *clee@hrsa.gov.*

Dated: February 10, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–3335 Filed 2–13–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Radionuclide Resource for Cancer Applications.

Date: March 16–18, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Chase Park Plaza, 212–232 North Kingshighway, St. Louis, MO 63108.

Contact Person: Sherwood Githens, PhD, Scientific Review Administrator, Special Review and Logistics Branch, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8068, Bethesda, MD 20892, (301) 435–1822.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 9, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–3303 Filed 2–13–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice